

Serial No. 09/912,957

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Please amend the subject application to read as follows:


In the claims:

1. (previously amended) A pharmaceutical composition which comprises orlistat and a pharmaceutically acceptable bile acid sequestrant selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex.

2-7 previously cancelled.

8. (previously amended) The composition according to claim 10, wherein pharmaceutically acceptable bile acid sequestrant is selected from the group consisting of β -cyclodextrin and γ -cyclodextrin.

9. previously cancelled

 10. (amended) A pharmaceutical composition which comprises orlistat and a pharmaceutically acceptable acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin.

11. (original) The composition according to claim 10, wherein the bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin.

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12. (original) The composition according to claim 11, wherein the bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, and sevelamer.

13. (original) The composition according to claim 12, wherein the bile acid sequestrant is cholestyramine.

14. (original) The composition according to claim 12, wherein the bile acid sequestrant is colestipol.

15. (original) The composition according to claim 12, wherein the bile acid sequestrant is sevelamer.

16. previously cancelled

17. (previously amended) The composition according to claim 1, wherein the composition comprises (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant.

18. (previously amended) The composition according to claim 17, which comprises:

- (a) from about 5 to about 1000 mg of orlistat;
- (b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex;
- (c) from about 0.1 to about 10 g of a filler;

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- (d) from about 0.05 to about 3.0 g of a surfactant;
- (e) from about 0.05 to about 2.0 g of a disintegrant;
- (f) from about 0.02 to about 2.0 g of a binder;
- (g) from about 0.001 to about 1.0 g of a lubricant;
- (h) from about 0.1 to about 5.0 g of a flowability enhancer;
- (i) from about 0.01 to about 4.0 g of a sweetener; and
- (j) and about 0.001 to about 0.5 g of a colorant.

19. previously cancelled

20. (amended) The compositions according to claim 17, wherein the orlistat is present in an amount of from about 10 to about 500 mg.

21. (amended) The composition according to claim 20, wherein the orlistat is present in an amount of about 120 mg.

22. (amended) The composition according to claim 20, wherein the orlistat is present in an amount of from about 20 to about 100 mg.

23. (amended) The composition according to claim 22, wherein the orlistat is present in an amount of about 60 mg.

24. never presented

25. (original) The composition according to claim 17, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g.

²⁵
26. (original) The composition according to claim ²⁴25, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g.

²⁶
27. (previously amended) A kit for use in the treatment of obesity, which comprises (a) a first component which is orlistat and (b) a second component which is a bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, γ -cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex, present in oral unit dosage form.

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28. (previously amended) A method of treating obesity in an obese patient, which comprises administering to a patient in need of such treatment (a) a therapeutically effective amount of orlistat and (b) a pharmaceutically acceptable bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, γ -cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex in an amount effective to reduce gastrointestinal side effects associated with the lipase inhibitor.

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29. (amended) The method according to claim ²⁷28, wherein the orlistat and bile acid sequestrant are administered simultaneously.

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30. (amended) The method according to claim ²⁷28, wherein the orlistat and bile acid sequestrant are administered separately.

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31. (amended) The method according to claim ²⁷28, wherein the orlistat and bile acid sequestrant are administered sequentially.

³¹
32. (previously amended) A method of reducing the gastrointestinal side effects associated with orlistat treatment, which comprises administering to a patient being treated with orlistat an amount of a bile salt sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, γ -cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex, effective to reduce the side effects associated with the orlistat treatment.

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33. (previously added) The composition according to claim 10, wherein the composition comprises (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant. --

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34. (previously added) The composition according to claim ³²33, which comprises:

- (a) from about 5 to about 1000 mg of orlistat;
- (b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin;
- (c) from about 0.1 to about 10 g of a filler;
- (d) from about 0.05 to about 3.0 g of a surfactant;
- (e) from about 0.05 to about 2.0 g of a disintegrant;
- (f) from about 0.02 to about 2.0 g of a binder;
- (g) from about 0.001 to about 1.0 g of a lubricant;
- (h) from about 0.1 to about 5.0 g of a flowability enhancer;
- (i) from about 0.01 to about 4.0 g of a sweetener; and
- (j) and about 0.001 to about 0.5 g of a colorant. --

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~~35~~. (previously added) The composition according to claim 13, wherein the composition comprises (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant.

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~~36~~. (previously added) The composition according to claim ³⁷~~35~~, which comprises:

- (a) from about 5 to about 1000 mg of orlistat;
- (b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β -cyclodextrin, and γ -cyclodextrin;
- (c) from about 0.1 to about 10 g of a filler;
- (d) from about 0.05 to about 3.0 g of a surfactant;
- (e) from about 0.05 to about 2.0 g of a disintegrant;
- (f) from about 0.02 to about 2.0 g of a binder;
- (g) from about 0.001 to about 1.0 g of a lubricant;
- (h) from about 0.1 to about 5.0 g of a flowability enhancer;
- (i) from about 0.01 to about 4.0 g of a sweetener; and
- (j) and about 0.001 to about 0.5 g of a colorant.

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~~37~~. (previously added) The compositions according to claim ³²~~33~~, wherein the orlistat is present in an amount of from about 10 to about 500 mg.

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~~38~~. (previously added) The composition according to claim ³⁶~~37~~, wherein the orlistat is present in an amount of about 120 mg.

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~~39~~. (previously added) The composition according to claim ³²~~33~~, wherein the orlistat is present in an amount of from about 20 to about 100 mg.

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40. (previously added) The composition according to claim ³⁸39, wherein the orlistat is present in an amount of about 60 mg.

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41. (previously added) The composition according to claim ³²33, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g.

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42. (previously added) The composition according to claim ⁴⁰41, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g.

⁴²
43. (previously added) The compositions according to claim ³⁹35, wherein the orlistat is present in an amount of from about 10 to about 500 mg.

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44. (previously added) The composition according to claim ⁴²43, wherein the orlistat is present in an amount of about 120 mg.

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45. (previously added) The composition according to claim ⁴²43, wherein the orlistat is present in an amount of from about 20 to about 100 mg.

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46. (previously added) The composition according to claim ⁴⁴45, wherein the orlistat is present in an amount of about 60 mg. --

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47. (previously added) The composition according to claim ³⁹35, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g.

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could
⁴⁷48. (previously added) The composition according to claim ^{4b}47, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g.
